

REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on January 10, 2008, claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997) in view of Elliot (US 1,885,401); and claims 1, 4-12 and 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998), in view of Gagnon (1997), in view of Brock et al. (1991), in view of Nahir (EP 0 555 573 A1) and in view of Elliot (US 1,885,410). For the reasons set forth below, Applicant submits that the prior art fails to teach or suggest all the claim limitations. Thus, Applicant's claims are not obvious in view of the prior art references.

1. The References Do Not Teach Every Claimed Limitation

Applicant submits that the cited references do not teach every aspect of the claimed invention, as amended. The method of making the product, and the various constitutive elements added to the product before delivery have a significant effect on lipidperoxidation inhibition. The specification of the present invention and the art cited against the present application outline the importance of the harvesting and processing steps in order to produce an improved *Morinda citrifolia* product, which has increased and unexpected capacity to inhibit lipidperoxidation.

The importance of the manufacturing steps utilized to process *Morinda citrifolia* products is confirmed in various published articles and by research performed by Applicant. The article [“Drug Development; The Pain Killer Tree: An Ancient Remedy Rediscovered” (hereinafter “Drug Development”)] clearly conveys that unexpected results were achieved when different processing steps are utilized. In particular, Drug Development taught that modifying a single processing step, utilizing freeze drying alone improved the efficiency of the noni product 267% over the closest other dried noni product. Congruent with the disclosure found in “Drug Development,” Chye discloses the concern that certain methods of manufacturing produce greater quality products, and that a Mr. Story and Wadsworth developed methods of harvesting, processing and bottling the juice that did not sacrifice the important effects natural ingredients.

Independent claim 1 recites a “method for processing and administering an improved *Morinda citrifolia* product with increased capacity to scavenge lipid hydroperoxides and

superoxide anion free radicals within the body, said method comprising: harvesting the fruit from a *Morinda citrifolia* plant; allowing fruit to ripen for 0 to 14 days; preparing said harvested fruit for extraction of the juice therefrom, wherein said preparing comprises: placing the ripened fruit in plastic lined containers, and holding the fruit in said containers for 0 to 30 days extracting the juice from said prepared fruit to obtain said *Morinda citrifolia* fruit juice, wherein said extraction comprises: [...] filtering by centrifuge decanter with a screen filter size between 1 and 2000 microns, wherein said operating filter pressure may range from about 0.1 psig to 1000 psig combining said processed *Morinda citrifolia* product with other ingredients [...]".

Chye, Schechter, Gagnon and Elliot fail to teach or fairly suggest the particular processing steps that produce a *Morinda citrifolia* product developed particularly to scavenge lipid hydroperoxides. Rather, Chye provides a non-enabling disclosure, which indicates merely that "noni-juice is the new darling of health-conscious Malaysians". Schechter indicates that noni fruit contains vitamin C, selenium, and other substances that counteract inflammation and absorb free radicals in the body. However, Schetheter does not disclose processing steps claimed herein that produce the surprising scavenging properties claimed in the present invention. And Elliot teaches a method of processing oranges into juice where the oranges are crushed, separating the rind and seeds from the pulp, juice, oil with a certain residue of seeds and rind. Elliot further teaches that the product is passed through a revolving screen of suitably large mesh to isolate the juice and that the separated liquid is subsequently passed through a centrifugal separator one or more times to remove the greater portion of the peel oil from the liquid mixture. Elliot does not teach allowing the fruit to ripen for 0 to 14 days; preparing said harvested fruit for extraction of the juice therefrom, wherein said preparing comprises: placing the ripened fruit in plastic lined containers, and holding the fruit in said containers for 0 to 30 days or the presently claimed method of extrating the juice from the prepared fruit to obtain said *Morinda citrifolia* fruit juice, wherein the extraction steps comprise the specific filtering requirements of filtering by centrifuge decanter with a screen filter size between 1 and 2000 microns, wherein said operating filter pressure may range from about 0.1 psig to 1000 psig. Accordingly, Elliot fails to recite each of the processing limitation and would not have put one skilled in the art in possession of the presently claimed juice product, even when combined with Chye, Schechter and Gagnon.

As the cited references fail to disclose or suggest all of the claim limitations of independent claims of the present invention, and further fail to suggest modifying the reference as suggested by the Examiner, the present invention is not obvious in view of such references.

2. The References Are Not Enabling

The Federal Circuit recently reaffirmed that in order for a reference to anticipate the claims in a pending application, it must provide a certain amount of disclosure: Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research, 346 F.3d 1051, 1055 (Fed. Cir. 2003). “Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not an enabling...” Id. Thus, in order for the cited art to render obvious the Applicant’s claims, it must put one skilled in the art in possession of all of the claim limitations.

Chye does not place into the public knowledge a process for processing the noni plant which preserves the natural efficacy of the plant during processing. But rather, indicates that Steven Story and John Wadsworth had developed and maintained a secret a process. Chye places the world in possession of the fact that a secret process exists, not in possession of the process for producing the product itself. Accordingly, Chye fails to teach or fairly suggest the process steps recited in the claims of the present invention.

As indicated above Schechter indicates that noni fruit contains vitamin C, selenium, and other substances that counteract inflammation and absorb free radicals in the body. However, Schetheter does not disclose processing steps claimed herein that produce the surprising scavenging properties claimed in the present invention. The composition as recited in the claims of the present invention has a scavenging affect which exceeds the regular intake of vitamin C and other known antioxidants. Experiments conducted in support of the present application indicated that the regular intake of the product of the present invention provides a stronger scavenging effect on superoxides and free radicals within the body than the regular intake of vitamin C, pycocogenol (Maritime pine bar extract), or grape seed powder. Specification, page 16, lines 6-15. While Schechter indicates that noni fruit has antioxidants, Schechter does not describe a method of processing and administering the noni fruit so as to provide an unexpected

scavenging effect as recited in the present invention, and accordingly does not put one skilled in the art in possession of all of the claim limitations.

Finally, as noted above, Elliot teaches limited processing steps for processing organges. But fails to the claimed processing steps for producing an improved *Morinda citrifolia* product with increased capacity to scavenge lipid hydroperoxides and superoxide anion free radicals. Accordingly, Elliots disclosure fails to place one skilled in the art at the time of invention in possession of all of the claim limitations.

For at least these reasons, Applicant respectfully submits that the prior art does not explicitly or impliedly teach every aspect of the invention as claimed in the independent base claims. In addition, the dependent claims place further limitations on otherwise allowable subject matter. Accordingly, Applicant respectfully submits that the cited art does not teach every aspect of the claims as provided herein, and therefore does not render the claims obvious.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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